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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,526	10/26/2001	Frederick H. Hausheer	X-0211	3276

7590

09/28/2004

Thomas J. Dodd
Senior Patent Counsel
8122 Datapoint Drive, Suite 1250
San Antonio, TX 78229

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT PAPER NUMBER

1614

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,526	HAUSHEER, FREDERICK H.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's Response filed July 12, 2004 is acknowledged. Claims 1-16 remain under consideration.

The objection of record set forth in the last Office Action is maintained. There is no period at the end of claim 16. The Examiner can no longer complete this correction. All applications are scanned.

Clarification is requested following Applicant's statement on page 2 of the Response filed July 12, 2004 under Remarks - "Claim 2 has been amended to identify dimensa (disodium 2,2'-dithiobis ethane sulfonate) as a preferred agent".

In the last Office Action the rejection of claims 1, 2 and 4 under 35 U.S.C. 102(b) as being anticipated by Plowman et al., Lancet, was maintained. Plowman teaches the parenteral administration of mesna, a compound of instant formula I, to provide radioprotection at a dose of 400 mg/kg.

Applicant argues Plowman's effective dose is nearly 70 times greater than the dose recommended for IV mesna.

The range recited in instant claim 2, from 0.1 mg/kg body weight to 1,000 mg/kg body weight encompasses Plowman's dose.

Because Plowman teaches the parenteral administration of mesna, a compound of instant formula I, to provide radioprotection at a dose of 400 mg/kg, the rejection of record under 35 U.S.C. 102(b) is maintained.

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Claims 1-4 were rejected in the last Office Action under 35 U.S.C. 103 as being unpatentable over van den Broeke et al., J. Photochem. Photobiol. It was asserted van den Broeke teaches the administration of mesna for UV radiation protection.

Following the amendment to claim 1 in which -- exposure to ionizing radiation -- replaced the original "radiation exposure", the rejection of record under 35 U.S.C. 103 is withdrawn.

Claims 1-16 were rejected under 35 U.S.C. 112, first paragraph, as lacking a clear written description of the invention and of the manner and process of practicing it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the same, and, as not setting forth the best mode contemplated by the inventor to carry out the invention.

The claims are directed to methods of treating a patient for exposure to ionizing radiation and of prophylactically treating a patient about to undergo radiation therapy comprising administering a compound of instant formula I, wherein R₁ is optionally "a sulfur-containing amino acid". The specification discloses no examples wherein an amino acid containing sulfur is utilized. This option finds no support in the specification. There is no showing that Applicant had possession of the claimed invention of therapeutic treatments comprising administering a compound of instant formula I wherein a sulfur-containing amino acid is utilized.

Applicant notes the rejection set forth *supra* was not present in the prior Office Actions and cites MPEP 2163.03.

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A new rejection may be set forth at any time during open prosecution. However, upon reconsideration, it clear what compounds are contemplated in the claimed genus of compounds. This rejection of record is withdrawn.

In the last Office Action claims 1-16 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to methods of treating a patient for exposure to ionizing radiation and of prophylactically treating a patient about to undergo radiation therapy comprising administering a compound of instant formula I. In the Examiner's view, the specification provides no support specifically directed to treatments wherein an outcome following the administration of such compounds shows any results whatsoever.

Applicant repeatedly argues about the placement of this rejection at this stage of prosecution and repeatedly alleges "incorrect and/or otherwise irrelevant statements and no factual evidence that could even begin to form a *prima facie* case of lack of enablement". Applicant argues results following the administration of a particular compound to treat a particular condition are not required in the presentation of working examples, or any "results" of experiments. The amount of guidance provided in the specification, Applicant alleges, has been ignored. Applicant urges the specification discloses a method of making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims.

A new rejection may be set forth at any time during open prosecution.

Particularly in view of the current rules of practice in the 1600 technology center, the rejection is proper. Further, the state of the art for treating exposure to ionizing radiation is immature. It is reasonable to require evidence that the goal of treating exposure from ionizing radiation comprising administering a compound of instant formula I has been achieved when such an accomplishment has never been attained. *In re Ferens*, 163 USPQ 609. Further, the failure of skilled scientists, whether they are radiologists or medicinal chemists, to achieve a goal is substantial evidence that attaining the goal is beyond the skill of practitioners in that art, *Genetech vs. Novo Nordisk*, 42 USPQ2nd 1001, 1006.

The rejection of claims 1-16 under 35 U.S.C. 112, first paragraph, is maintained. The specification does not disclose a method of using the claimed invention that bears a reasonable correlation to the entire scope of the claims.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Phyllis G.

Spivack at telephone number 571-272-0585.



Phyllis G. Spivack
Primary Examiner
Art Unit 1614

September 26, 2004

PHYLLIS SPIVACK
PRIMARY EXAMINER